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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,054	02/08/1999	MICHAEL TERENCE BLACK	GM50023	9484

7590 12/28/2010  
AUTHUR JACKSON  
DECHERT PRICE & RHOADS  
1717 ARCH STREET  
4000 BELL ATLANTIC TOWER  
PHILADELPHIA, PA 19103-2793

EXAMINER
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DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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12/28/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

09/242,054

**Applicant(s)**

BLACK ET AL.

**Examiner**

S. Devi, Ph.D.

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_

## **Lack of Unity**

- 1)** Claims 1-26 are under prosecution.
- 2)** As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

- 3)** As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

**4)** Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-9, 25 and 26, drawn to an isolated polynucleotide, a vector and a host cell.
- II. Claims 10-12, drawn to a method of using the host cell or vector of invention I.
- III. Claims 13 and 14, drawn to a polypeptide comprising an amino acid sequence at least 70% identical to SEQ ID NO: 2 or 4.
- IV. Claim 15, drawn to an antibody against the polypeptide of invention III.
- V. Claim 16, drawn to an antagonist that inhibits the activity of the polypeptide of invention III.
- VI. Claims 17 and 18, drawn to a method for treatment comprising administering the polypeptide of invention III.
- VII. Claim 19, drawn to a method of treatment comprising administering the antagonist of invention V.

- VIII. Claim 20, drawn to a process for diagnosing a disease comprising determining a nucleic acid sequence encoding the polypeptide of invention III.
- IX. Claim 21, drawn to a diagnostic process comprising analysing the presence of the polypeptide of invention III.
- X. Claim 22 (in part), drawn to a method for identifying compounds that inhibit the activity of the polypeptide of invention III.
- XI. Claim 22 (in part), drawn to a method for identifying compounds that activate the activity of the polypeptide of invention III.
- XII. Claim 23, drawn to a method of inducing an immunological response comprising inoculating with ratA, a fragment or variant thereof.
- XIII. Claim 24, drawn to a method of inducing an immune response comprising delivering nucleic acid vector expressing ratA.

**5)** Inventions I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The special technical feature of the first claimed invention is an isolated polynucleotide comprising at least 15 sequential bases of SEQ ID NO: 1 or 3, or having at least 70% identity thereto. However, such a polynucleotide was already disclosed in the art at the time of the invention by Kunsch et al. (US 6,420,135).

AR218775  
LOCUS AR218775 19702 bp DNA linear PAT 25-SEP-2002  
DEFINITION Sequence 7 from patent US 6420135.  
ACCESSION AR218775  
VERSION AR218775.1 GI:23319709  
KEYWORDS .  
SOURCE Unknown.  
ORGANISM Unknown.  
UNCLASSIFIED.  
REFERENCE 1 (bases 1 to 19702)  
AUTHORS Kunsch,C.A., Choi,G.H., Dillon,P.S., Rosen,C.A., Barash,S.C.,  
Fannon,M.R. and Dougherty,B.A.

TITLE		Streptococcus pneumoniae polynucleotides and sequences	
JOURNAL		Patent: US 6420135-A 7 16-JUL-2002;	
		Human Genome Sciences, Inc.; Rockville, MD;	
		WOX;	
FEATURES		Location/Qualifiers	
source		1. .19702	
		/organism="unknown"	
		/mol_type="genomic DNA"	
ORIGIN			
Query Match		96.9%; Score 1419.2; DB 9; Length 19702;	
Best Local Similarity		98.1%;	
Matches 1436; Conservative		0; Mismatches 28; Indels 0; Gaps 0.	
Qy	1	ATGACTTTTAAACAATAAAACTATTGAAGAGTTCGCAACATCTCCTTGCTCTAAGGAAATT	60
Db	3225	ATGACTTTTAAACAATAAAACTATTGAAGAGTTCGCAACATCTCCTTGCTCTAAGGAAATT	3284
Qy	61	CTCGCAACAGAATTGACCCACGCAACACTTGAAATATCAAGTCTCGTGAGGAAGCCATC	120
Db	3285	CTCGCAACAGAATTGACCCACGCAACACTTGAAATATCAAGTCTCGTGAGGAAGCCCTC	3344
Qy	121	AATTCAATTGTCCACCATCGCTGAGGAGCAAGCTCTTGTTCAAGCTAAAGCCATTGATGAA	180
Db	3345	AATTCAATTGTCCACCATCGCTGAGGAGCAAGCTCTTGTTCAAGCTAAAGCCATTGATGAA	3404
Qy	181	GCTGGAATTGATGCTGACAAATGTCTTTCAGGAATTCACATGTGCTGTAAGGATAACATC	240
Db	3405	GCTGGAATTGATGCTGACAAATGTCTTTCAGGAATTCACATGTGCTGTAAGGATAACATC	3464
Qy	241	TCTACAGACGGTATTCTCACAACGTGCTGCCCTCAAAAATGCTCTACAACATATGAGCCAACT	300
Db	3465	TCTACAGACGGTATTCTCACAACGTGCTGCCCTCAAAAATGCTCTACAACATATGAGCCAACT	3524
Qy	301	TTTGATGCGACAGCTGTGCCAAATGCAAAAACCAAGGCATGATTGTCGTTGGAAGACC	360
Db	3525	TTTGATGCGACAGCTGTGCCAAATGCAAAAACCAAGGCATGATTGTCGTTGGAAGACC	3584
Qy	361	AACATGGACGAATTGTGCTATGGGTGGTTCAGGTGAAACTTCACATACGGAGCAACTAAA	420
Db	3585	AACATGGACGAATTGTGCTATGGGTGGTTCAGGTGAAACTTCACATACGGAGCAACTAAA	3644
Qy	421	AACGCTTGGGACCAACAGCAAGGTTCTCGTGGGTGCATCAAGTGGTTCGCGCCAGCTGTA	480
Db	3645	AACGCTTGGGAACCAACAGCAAGGTTCTCGTGGGTGCATCAAGTGGTTCGCGCCAGCTGTA	3704
Qy	481	GCCTCAGGACAAGTTCGCTTGTCACCTGGTTCGTATACGGTGGTTCATCCGCGCAACCT	540
Db	3705	GCCTCAGGACAAGTTCGCTTGTCACCTGGTTCGTATACGGTGGTTCATCCGCGCAACCT	3764
Qy	541	GCTGCCTTCAACGGAATCGTTGGTCTCAAAACCAACTACGGAACAGTTTCAGGTTTCGGT	600
Db	3765	GCTGCCTTCAACGGAATCGTTGGTCTCAAAACCAACTACGGAACAGTTTCAGGTTTCGGT	3824
Qy	601	CTCATTGCCTTTTGGTAGCTCATTAGACAGATTGGACCTTTTGCTCCTACTGTTAAGGAA	660
Db	3825	CTCATTGCCTTTTGGTAGCTCATTAGACAGATTGGACCTTTTGCTCCTACTGTTAAGGAA	3884
Qy	661	AATGCCCTCTTGCTCAACGCTATTGCCAGCGAAGATGCTAAAGACTCTACTTCTGCTCCT	720

Db	3885	AATGCCCTCTTGCTCAACGCTATTGCCAGCGAAGATGCTAAAGACTCTACTTCTGCTCCT	3944
Qy	721	GTCCGCATCGCCGACTTTACTTCAAAAATCGGCCAAGACATCAAGGGTATGAAAATCGCT	780
Db	3945	GTCCGCATCGCCGACTTTACTTCAAAAATCGGCCAAGACATCAAGGGTATGAAAATCGCT	4004
Qy	781	TTGCCTAAGGAATACCTCGGTGAAGGAATTAAACCCAGAGGTTAAGGAAACCATTTCTAAAT	840
Db	4005	TTGCCTAAGGAATACCTAGCGCAAGGAATTGATCCAGAGGTTAAGGAAACCAATCTTAAAC	4064
Qy	841	GCCGCTAAACACTTTGAAAAATTGGGTGCTATTGTGGAAGAGTCAGCCTTCCTCACTCT	900
Db	4065	GCGGCCAAACACTTTGAAAAATTGGGTGCTATCGTGAAGAGTCAGCCTTCCTCACTCT	4124
Qy	901	AAATACGGAGTTGCCGTATACTACATCATCGCTTCATCAGAAGCTTCATCAAACTTGCAA	960
Db	4125	AAATACGGTGTTCGCGTTTATTACATCATCGCTTCATCAGAAGCTTCATCAAACTTGCAA	4184
Qy	961	CGCTTCGACGGTATCCGTTACGGCTATCGCGCAGAAGATGCAACCAACCTTGATGAAATC	1020
Db	4185	CGCTTCGACGGTATCCGTTACGGCTATCGCGCAGAAGATGCAACCAACCTTGATGAAATC	4244
Qy	1021	TATGTAAACAGCCGAAGCCAAGGTTTGGTGAAGAAGTGAAGCGCCGATATCATGCTGGGT	1080
Db	4245	TATGTAAACAGCCGAAGCCAAGGTTTGGTGAAGAAGTAAAACGTCGTATCATGCTGGGT	4304
Qy	1081	ACTTTCAGTCTTTTCATCAGGTTACTACGATGCCTACTATAAGAAGGCTGGACAGGTCCGT	1140
Db	4305	ACTTTCAGTCTTTTCATCAGGTTACTATGATGCCTACTACAAAAGGCTGGTCAAGTCCGT	4364
Qy	1141	ACACTTATCATTCAGGATTTCGAAAAAGTCTTCGCGGATTACGATTGATTTGGGTCCA	1200
Db	4365	ACCCTCATTCATTCAGGATTTCGAAAAAGTCTTCGCGGATTACGATTGATTTGGGTCCA	4424
Qy	1201	ACTGCTCCAAGTGTGCCTATGACTTGGATTCTCTCAACCATGACCCAGTTGCCATGTAC	1260
Db	4425	ACTGCTCCAAGTGTGCCTATGACTTGGATTCTCTCAACCATGACCCAGTTGCCATGTAC	4484
Qy	1261	TTAGCCGACCTATTGACCATACTGTAAACTTGGCAGGACTGCCTGGAATTTGATTCCCT	1320
Db	4485	TTAGCCGACCTATTGACCATACTGTAAACTTGGCAGGACTGCCTGGAATTTGATTCCCT	4544
Qy	1321	GCTGGATTCTCTCAAGGTCTACCTGTCGGACTCCAATTGATTGGTCCCAAGTACTCTGAG	1380
Db	4545	GCTGGATTCTCTCAAGGTCTACCTGTCGGACTCCAATTGATTGGTCCCAAGTACTCTGAG	4604
Qy	1381	GAAACCATTTACCAAGCTGCTGCTGCTTTTGAAGCAACACAGACTACCACAAACACAA	1440
Db	4605	GAAACCATTTACCAAGCTGCTGCTGCTTTTGAAGCAACACAGACTACCACAAACACAA	4664
Qy	1441	CCCGTGATTTTGGAGGTGACAAC	1464
Db	4665	CCCGTGATTTTGGAGGTGACAAC	4688

Thus, the special technical of the first claimed invention is taught by the prior art, and therefore does not define over the prior art. Although the first claimed product of invention I, the method of making the product, and the method of using the

product, is a permitted combination under PCT Rule 13.2, in the instant case, since the product is already disclosed in the art, the special technical feature is not a unifying feature. Technically, the absence of special technical feature permits the separation of the method of using or making the product from the product itself. The special technical features of the subsequently claimed inventions are delineated above. The polypeptide of invention III, the antibody of invention IV, and the antagonist of invention V, do not share significant common structure with the polynucleotide of invention I. A polypeptide is a single chain molecule which comprises amino acid residues. A nucleic acid molecule comprises purine and pyrimidine units. An antibody is a glycoprotein which includes IgG that comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. An antagonist is a chemical compound. Furthermore, the polynucleotide of invention I, the polypeptide of invention III, the antibody of invention IV and the antagonist of invention V, are divergent with regard to their composition, structure, function, and class or subclass, each requiring separate and non-coextensive searches. Furthermore, the methods of inventions II and VI-XIII do not share significant common method steps and parameters, products or reagents used, method objectives and/or the ultimate goals accomplished.

**6)** With regard to invention III and inventions VI-VIII, the Office has separated product and process claims based on restriction. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of

MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

**7)** In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper lack of unity between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See ‘Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)’, 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

**8)** Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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**9)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

**10)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

**11)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's acting Supervisor, Patricia Duffy, can be reached on (571) 272-0855.

/S. Devi/  
Primary Examiner  
AU 1645

December, 2010